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LASER PRODUCTS

Performance Standards

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CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER J—RADIOLOGICAL HEALTH

[Docket No. 75N-0103]

PART 1010—PERFORMANCE STANDARDS FOR ELECTRONIC PRODUCTS: GENERAL

PART 1040—PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS

Performance Standard for Laser Products

The Commissioner of Food and Drugs proposed in the FEDERAL REGISTER of December 10, 1973 (38 FR 34084), to amend Chapter I of Title 21 of the Code of Federal Regulations by adding to Subchapter J a new Part 1040, prescribing a radiation safety performance standard for laser products in new §§ 1040.10 and 1040.11, and by amending Part 1010 to apply to new Part 1040.

In consideration of comments submitted, and to provide further clarification, the proposed standard was revised and republished in the FEDERAL REGISTER as a notice of proposed rulemaking on September 4, 1974 (39 FR 32094). Thirty days were provided for public comments.

On the basis of comments submitted and for purposes of clarification, the standard has been revised and under authority of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b through 263n) is issued herein as an amendment to Chapter I, of Title 21 of the Code of Federal Regulations.

The need for such a standard was based upon several factors, including the increasingly widespread use of a variety of commercial laser products in environments ranging from restricted industrial locations to completely unrestricted public areas. Such products pose varying degrees of radiation hazards to persons in these environments. The hazard depends upon the type, magnitude, and accessibility of laser radiation which the products produce and upon the particular function or operation which they are intended to perform. Serious radiation injuries associated with accidental exposure to laser beams have been reported to the Food and Drug Administration (FDA). Surveys of laser products in high schools, colleges and industrial installations also indicate the need for additional protective features on laser products.

The purpose of this standard is to protect the public health and safety from the danger of laser radiation by assuring adequate warning to individuals of the hazards associated with accessible radiation from laser products and by reducing the possibility of injury by minimizing unnecessary accessible radiation. The requirements provide for adequate identification of radiation hazards through labels and instructions, containment of unnecessary radiation, and protective features to give the operator improved control of the radiation.

Comments on the second notice of proposed rule making (39 FR 32094) were received from a trade association representing manufacturers of laser products, a physics education association representing users of laser products, the Occupational Safety and Health Administration in the Department of Labor, the Veterans Administration, a State health department, and numerous individual manufacturers of laser products. These comments, the Commissioner's analysis and his final action are summarized as follows:

1. Two comments concerning the definition of "Class I laser product" in § 1040.10(b)(5) contended that the manufacturer's intended use of a product is a sufficient basis for the selection of the maximum emission duration in Table I–A to classify a product as Class I. Specifically, it was suggested that there should be included in the regulation a provision for Class I laser products not intended by the manufacturer for chronic viewing, but which might accidentally be viewed only for much shorter intervals.

The Commissioner concludes that a manufacturer of laser products cannot always know how his products may be used. Therefore, he cannot assure that chronic or long-term viewing will not occur. Because the performance standard must be based on the inherent emission characteristics of the product, the Commissioner concludes that only if the possibility of chronic exposure can be limited by product design would classification be based upon an emission duration consistent with such limitation. The standard does allow this option by basing the accessible emission limits upon the cumulative energy emitted during a particular emission duration.

2. One comment concerning the definition of "Demonstration laser product" in § 1040.10(b)(10) contended that, since a manufacturer's intended function for the product may not be limited to those representations made in his advertising, he might be held in violation of the standard if any of his laser products are used for demonstration purposes by the user and if it could not be proved that the manufacturer did not intend such use at the time of sale.

The Commissioner concludes that although the manufacturer cannot always know the manner in which a product is actually used, he does control how his product is designed and promoted, and may specify possible applications. The manufacturer is responsible for compliance with the requirements for a demonstration laser product only if the product is "manufactured, designed, intended, or promoted for purposes of demonstration."

3. Concerning the Commissioner's statement in the preamble of the proposal published in the FEDERAL REGISTER of September 4, 1974 (39 FR 32094), that the standard in no way prohibits the purchase and use of any laser product for any purpose, one comment asked how a user, under § 1040.11(c) of the proposed rule, could purchase from a manufacturer a demonstration laser product of a class higher than Class II.

The FDA has no authority over the manner in which electronic products are used. Thus, while a manufacturer is prohibited from selling a laser product which is "manufactured, designed, intended or promoted for purposes of demonstration" and which has an accessible emission level in excess of the Class II limit, the standard does not prohibit the purchase of other laser products, of any classification, for any purpose.

4. Another comment stated that the definition of "demonstration laser product" could be interpreted to exclude a general purpose CW visible 5mW laser not designed, intended, or promoted for demonstration purposes. The comment further suggested clarifying the definition of "demonstration laser product" to include lasers used in classroom environments and to exclude laser products which are manufactured "primarily" for other applications, such as laboratory experiments or research.

The Commissioner agrees that a CW visible 5mW laser can be sold as a general purpose laser even though it may be used for demonstration purposes by the user. The Commissioner also concludes that specific reference to use in classroom environments is unnecessary and that insertion of the word "primarily" in the definition is unacceptable. The intent as expressed in the revised definition is that no laser product which is "manufactured, designed, intended, or promoted" for demonstration purposes may exceed the Class II limits, regardless of any other intended use.

5. Several comments stated that the use of the terms "emission duration" and "sampling interval," as defined in § 1040.10(b) (11) and (32), is ambiguous. In particular, one comment asked how long an emission duration a manufacturer should consider in determining compliance with the standard.

The Commissioner agrees that the terms can be used more appropriately to clarify the standard, and the final rule has been revised accordingly. The term "emission duration" is employed to refer to an emission characteristic of the product while the term "sampling interval" refers to a characteristic of the measurement process for applying the accessible emission limits to the laser output. The maximum emission duration which needs to be considered in most cases is the lower boundary of the highest range of emission duration in Tables I–A, I–B, and I–C, because the accessible emission limit in effect becomes a power criterion above that boundary. Furthermore, the actual measurement sampling interval need not be as long as such maximum emission duration, if a reliable extrapolation can be made into the highest emission duration range.

6. One comment concerning the definition of "human access" in § 1040.10(b)(12) stated that since some probes could reach through small cracks without constituting a hazard, the diameters of the test probe should be specified in the definition. Another comment suggested that the spatial location of probe

entry with respect to the axis of the laser beam should be stated.

The Commissioner concludes that very small diameter probe types may be used in testing for "human access." Because current research and development leads to the production of very small diameter optical probes, such as optical fibers, a minimum diameter for a test probe should not be specified. Furthermore, it is impractical to specify the orientation of the probe with respect to the laser beam since testing may involve more than one geometric configuration. The Commissioner also concludes that even "small cracks" can constitute a hazard, especially considering the possibility of insertion of objects into such cracks. Such insertion could result in access to laser radiation and thereby pose a risk of human injury from the reflected radiation.

7. Two comments objected to the definition of "human access" in § 1040.10(b)(12) because it could be interpreted to include human access during service, especially as a basis for classification, and suggested modification of the definition to exclude service.

The Commissioner agrees that in certain instances the definition includes human access during service, but intends that each requirement of the standard delineate whether it is necessary to test human access during operation, maintenance, or service as stated in § 1040.10(e)(2)(iii). For example, since classification is based upon operation, human access is tested only over the full range of operational capability, and not with the product in a service configuration. However, other requirements of the standard do require human access to be tested under service conditions.

8. Another comment concerning § 1040.10(b)(12) questioned the rationale used in defining the length of probes for determining "human access," and stated that a distance of 100 centimeters would not attenuate radiation to a safe level.

The Commissioner notes that the 100-centimeter length was not intended to represent a safe distance, but was intended as a reasonable distance beyond the point of closest approach by any part of the human body, including the eye, for testing human access. The reference to the 10-centimeter length in this definition takes into account the existence of small, flexible optical fibers, which can be used to probe very small openings and therefore permit human access to laser radiation.

9. One comment observed that the definition of "human access" in §1040.10(b)(12) appeared to include both a concept and a test specification. The comment included the recommendation to delete the test specification from the definition and, instead, to add other access criteria such as reflection or conduction of laser or collateral radiation. Another comment suggested using a line of sight 100 centimeters or less in length and a curved or baffled line 10 centimeters or less in length to define human access by other than a part of the human body, rather than by a test object.

The Commissioner agrees that the definition should be further clarified. However, access by reflection or conduction cannot be adequately defined for measuring purposes. The suggested line-of-sight and curved line concept correctly expresses the intent, and therefore this concept is accepted. The definition of human access in § 1040.10(b)(12) is reworded by referring to access by a straight line having an unobstructed length of 100 centimeters, or by any line having an unobstructed length of 10 centimeters.

10. One comment noted that the definition of "laser" in § 1040.10(b)(15) might be interpreted to include "SRL sources," which are small discs of semiconductor granules, such as cadmium sulfide, as laser products since, when bombarded by electron beams, they produce stimulated but incoherent emission. However, the only control of such emission is that of excitation by the electron beam.

The present definition of "laser" was not intended to include such sources, and the Commissioner concludes that the definition should not be amended. However, the Food and Drug Administration will continue to explore and review the need for future revision of the scope of the definition.

11. One comment stated that the definition of "laser product" in § 1040.10(b)(17) and the definition of "surveying, leveling and alignment laser products" in § 1040.10(b)(35) could be construed to include products intended solely for research and development and not for sale.

The Commissioner concludes that, generally, products used solely by their manufacturer for in-house research and development purposes would not be subject to the standard. The performance standard would apply to all laser products as defined in § 1040.10(b)(17) which any person is engaged in the business of manufacturing, assembling or importing. While most laser products are intended for sale or other transfer, there may be situations in which a person who fabricates or assembles laser products for use in his business might be considered a manufacturer of a laser product subject to the standard. In all cases, developmental prototypes of commercial laser products would be subject to the standard when delivered to a user for field testing, even if the manufacturer retains ownership or control of such prototypes.

12. One comment stated that since lasers and laser systems sold directly to a manufacturer of an electronic product for use as replacement components would not be subject to the standard under § 1040.10(b)(17), as proposed in the FEDERAL REGISTER of September 4, 1974 (39 FR 32094), identical replacement components should also be excluded from the requirements of the standard if sold by the manufacturer or his component supplier directly to a service organization or ultimate user. The comment further stated that lasers and laser systems manufactured after the effective date of the standard should not have to comply with the standard if they are sold for use as replacement components in electronic products manufactured before the effective date of the standard.

The Commissioner agrees that alternate methods of distributing replacement components should not result in some being subject to the performance standard while identical components, shipped under another distribution plan, are not, provided the manufacturer of the final product would be responsible for compliance of the complete and final laser product containing the replacement components. Therefore, § 1040.10(a) has been revised to exclude laser products from the applicability of the standard when sold either as original or replacement components directly "to" another manufacturer, or to a final product user or service organization under any circumstances in which such components are labeled for such use and sold "by" or "for" the manufacturer of the final certified laser product with adequate installation instructions so that such manufacturer is legally responsible for compliance with the standard of the complete and final products containing such components. For example, a user of the final product or a service organization could submit a component purchase order to the manufacturer of the final product and either he or his component manufacturer could ship the labeled laser component with installation instructions, or the component manufacturer could receive purchase orders directly from such a user or service organization, as long as the final product manufacturer accepts responsibility for the components when installed in his products. However, because § 1040.10(c)(2) also makes subject to the standard removable laser systems that are intended for use in products subject to the standard, any such removable laser system that is capable of independent operation without modification as described in paragraph (c)(2) would be subject to the standard when sold directly to a user or service organization, even when sold by or for the final product manufacturer.

In all cases, § 1040.10(a) provides that only laser products which are manufactured or assembled on or after the effective date of the standard will be subject to its requirements. Therefore, the Commissioner concludes that a final laser product manufactured before the effective date of the standard would not be subject to the standard, even if a component laser or laser system were replaced by one manufactured after the effective date. Furthermore, the replacement laser or laser system itself would not be subject to the standard, although manufactured after the effective date, if it were sold either to, for, or by the manufacturer of the old final product. Even removable laser systems replaced in products manufactured before the effective date would not be subject to the standard, if sold to, for,

or by the manufacturer of the old product since § 1040.10(c)(2) has been clarified to apply only to those removable laser systems used as components of products subject to the standard. However, all lasers and laser systems manufactured after the effective date of the standard for use as components of an electronic product would be subject to the standard if not sold by, to, or for the manufacturer of such electronic product, regardless of when the electronic product was manufactured, because they would be laser products under § 1040.10(b)(17) which are not excluded by § 1040.10(a).

13. Three comments concerning Table I–A in § 1040.10(d) contended that recent biological evidence exists to support a lower chronic exposure hazard potential for Helium-Neon laser products than is used as a basis for the Class I accessible emission limits for visible laser radiation.

The Commissioner has reviewed the experimental data submitted with the comments and concludes that such data support the present general Class I accessible emission limits for visible wavelengths, and that the data specifically for Helium-Neon laser radiation are insufficient to indicate a need for changing the Class I limits for that wavelength.

14. One comment suggested that the Class I dual limits in § 1040.10(d)(4) were included to accommodate highly divergent sources such as the gallium-arsenide (GaAs) junction diode, and that the proposed rule may not fully take into account the less stable optical emission frequency and the lesser coherence believed to characterize the output of GaAs diodes. Further, the comment suggested that the standard should provide additional guidance concerning the use of the integrated radiance alternative for classifying laser products under conditions where the beam approaches the collimated case.

The Commissioner notes that the Class I accessible emission limits for radiant energy were based on data which included tests with GaAs laser diodes. The intent of the integrated radiance alternative is to accommodate extended sources (real or virtual) such as holographic images, diffuse reflections, transmissions through diffusers, or diffuse collateral radiation. If the concept of integrated radiance is considered for GaAs output, either the source area or the intrinsic divergence (or both) are small, yielding a radiance which is too high to be used as the alternative for classification. However, the dual limits of Class I are exceeded only if both the limits for radiant energy and integrated radiance are exceeded.

15. One comment stated that the requirement concerning tests for certification in § 1040.10(e)(1) to account for measurement error and uncertainty is unnecessarily stringent and without precedent. It was suggested that measurement error and uncertainty should be included only to the extent that they exceed ±20 percent. Another comment suggested deleting the requirement to account for degradation of radiation safety with age.

The Commissioner concludes that the requirement is not unnecessarily restrictive. Since the manufacturer must assure that each product which he certifies does not exceed the accessible emission limits applicable to that product at any time after manufacture, his test and testing program for certification must take into account all measurement uncertainty as well as increases in emission and degradation of the product with age. Failure to do so could result in some products permitting human access to radiation above the limits upon which certification was based or otherwise failing to comply with the standard.

16. One comment concerning § 1040.10(e)(2)(ii), regarding test conditions, stated that since this provision requires maximizing those controls and adjustments listed in user or service instructions, a manufacturer could avoid having to maximize pre-set factory adjustments, when testing for compliance, by not listing those adjustments in such instructions. The comment also interpreted "functional integrity" to mean satisfactory operation and not physical damage. Another comment stated that § 1040.10(e)(2)(ii) should not require tests to be made during servicing, with service controls set for maximum radiation emission, when determining compliance with the Class I transmission limit for viewing optics under § 1040.10(f)(8), because typical service procedures would take less than 10^4 seconds, and adjusting service controls beyond the point of maximum accessible emission during operation would render the product inoperable and therefore not present a chronic hazard to the user.

The Commissioner notes that § 1040.10(h)(2)(ii) concerning servicing informational requirements requires all controls, including pre-set factory adjustments, to be listed in instructions available to the user if they "could be utilized by persons other than the manufacturer or his agents to increase accessible emission levels of radiation." Section 1040.10(e)(2)(ii) requires adjusting all such listed controls for the maximum accessible radiation under the appropriate conditions during operation, maintenance or service for testing compliance with a particular requirement of the standard. The Commissioner concludes that product classification pursuant to § 1040.10(c)(1) is determined only during "operation," as defined in § 1040.10(b)(23). Therefore, when testing classification or other requirements applicable during operation, the listed controls only need to be adjusted for the maximum level of radiation accessible during operation. For example, a product whose function is simply to emit laser radiation would be in "operation" whenever it emits laser radiation and would be classified on the basis of the highest level of accessible laser radiation that could be emitted. A product with more specialized functions would be considered in "operation" whenever there is no clear indication of malfunctioning and would be classified on the basis of the highest level of laser radiation which could be accessible without such clear indication of malfunctioning.

When determining compliance with a requirement of the standard which applies during maintenance or service, such as the Class I transmission limit for viewing optics in § 1040.10(f)(8), the listed controls would have to be adjusted for the maximum accessible radiation during such maintenance or service. However, if adjustment for maximum accessible radiation could damage the product, § 1010.13 permits the use of alternate test procedures, but compliance with the particular requirement would still be based on the projected highest accessible emission level. Because viewing optics invite chronic eye exposure and the manufacturer cannot be certain that service procedures could not result in such chronic exposure, the Commissioner concludes that § 1040.10(f)(8) should restrict transmission of radiation by viewing optics to less than Class I at all times, including during service. Likewise, because some service controls may affect the accessible levels of radiation during operation, maintenance, and service, the Commissioner concludes that § 1040.10(e)(2)(ii) should include adjustment of service controls, with the language revised to clarify the test conditions.

17. According to one comment, § 1040.10(f)(2) concerning safety interlocks implies that an electrical interlock switch is not sufficiently reliable, possibly based on an assumption that the protective housing will be removed frequently. The comment suggested alternative language which would permit use of redundant electrical interlock switches as an alternative to the other interlock requirements for portions of the protective housing removed only infrequently; if it can be demonstrated that the expected usage is less than 40 percent of the reliability of the circuit. It was also stated that § 1040.10(f)(2)(i) does not appear to permit protective housing warning labels as an alternative to safety interlocks, while § 1040.10(g)(6) apparently does.

Manufacturers cannot conclusively predict nor control the frequency of use of a safety interlock; therefore, the Commissioner concludes that such a prediction should not be used as a basis for defining the reliability of the interlock. A safety interlock employing an electrical switch is not necessarily unacceptable if, upon its failure, removal of the protective housing would be precluded either by an independent monitor or by a built-in fail-safe design. Assuming equally high reliability of individual electrical switches, the approach required by the standard is more reliable than redundant interlocks. Should either redundant interlock fail, such failure would not be apparent until the other interlock also failed. However, if the proposed monitored or fail-safe interlock failed, the failure would be made apparent by the inability to remove the protective housing and could be repaired before hazardous exposure could occur. Only prior failure of the independent monitor function would not be apparent until the inter-

lock also failed. Thus, complete failure of an interlock system resulting in hazardous exposure is less probable with a monitored or fail-safe interlock than with a redundant interlock.

Concerning the second portion of this comment, § 1040.10(g)(6) does not permit a general alternative between safety interlocks and protective housing warning labels, but rather requires warning labels whenever safety interlocks are either not required by § 1040.10(f)(2)(i) or not voluntarily provided in lieu of warning labels. Thus, a portion of the protective housing designed to be removed only during service could have either a safety interlock or a warning label. However, a protective housing portion designed to be removed during operation or maintenance would have to be interlocked, unless it is designed to be removed during operation only when access to the resultant levels of radiation is necessary to perform the intended function of the product.

18. Two comments stated that the requirements in § 1040.10(f) (3), (4), (5), and (6) for remote control connectors, key controls, emission indicators and beam attenuators, respectively, add no additional safety to laser systems which emit less than 5 milliwatts in the visible wavelength range of 400 to 700 nanometers. Another comment agreed and suggested that low power laser products have an insignificant hazard potential, and that the imposition of these requirements on low power products is unnecessary and could be detrimental to the public health and safety because users faced with "overly conservative safety measures" tend to ignore all safety measures. In addition, the comments contended that imposition of these requirements for many such products would be wasteful of resources and result in substantial increased cost.

The Commissioner notes that Class II laser systems under chronic exposure conditions may cause permanent retinal burns, and that such risks also are posed by Class III laser sytsems under chronic, as well as certain acute, exposure conditions for laser radiation of less than 5 milliwatts in the visible wavelength range. Hence, these requirements are not overly conservative. The Commissioner concludes that remote control connectors and key controls are needed to permit better control and prevent unauthorized operation of acutely hazardous laser products. The Commissioner also concludes that the emission indicator will alert the user when hazardous laser radiation is accessible and that such indication is needed, along with a beam attenuator to control such access since many laser products of this type are used in relatively unrestricted areas such as classrooms. Furthermore, the Commissioner believes, on the basis of manufacturers' reports required by 21 CFR Part 1002, that such safety features as presently incorporated in many products provide suitable indication and control of laser radiation, and do not result in excessive cost. Modification of the scope of these requirements is therefore not in the interest of public health and safety.

19. Other comments concerning § 1040.10(f)(5) expressed concern over the difficulty in meeting the proposed requirement that the emission indication be provided immediately before the emission of accessible laser radiation in excess of the limits of Class I. More specifically, it was pointed out that the words "immediately before" could mean a time too short to adequately react to the ensuing emission for some laser products, that the requirement precludes the use of the laser power circuit turning on the alarm, and that the proposed requirement for predicting or sensing a Class II, III or IV laser beam adds complexity of design. One comment recommended that the emission indicator concept be changed to one of an indication that the laser system power supply is energized and there is a likelihood of emission.

It was always the intent of the Food and Drug Administration that, for Class II laser products, the use of the laser energy source to actuate the emission indicator would be acceptable. Thus, a pilot light as presently incorporated in such products may be a suitable indication of laser radiation. Therefore, to clearly set forth the intent with regard to the emission indicator for Class II laser systems the words "immediately before" have been deleted and the language in § 1040.10(f)(5) has been revised. The emission indicator requirements for Class II laser systems are now specified in § 1040.10(f)(5)(i), (iii), (iv), and (v).

Concerning Class III or IV laser systems, the intent of the proposed requirements for a visible or audible indication "immediately before and during" the emission of accessible laser radiation was to provide a warning during emission and sufficiently in advance of emission so that appropriate action can be taken. The Commissioner agrees that for some laser systems the words "immediately before" could mean a time too short to react appropriately to the ensuing emission. However, the recommended indication that the laser system power supply is energized may not provide an adequate warning for all laser systems when laser radiation is being emitted. Further, no documentation was submitted to support the recommendation to delete the requirement for a warning sufficiently prior to and during the emission of accessible laser radiation for Class III and Class IV laser systems. The Commissioner concludes, therefore, that the intent of FDA with regard to this requirement must be retained, but for Class III and IV laser systems the language has been clarified by deleting the phrase "immediately before" and adding the phrase "sufficiently prior to emission of such radiation to allow appropriate action to avoid the laser radiation." The emission indicator requirements for Class III and Class IV laser products are specified in § 1040.10(f)(5)(ii), (iii), (iv), and (v).

20. Another comment on § 1040.10(f)(5) recommended that an audible emission indicator should include specification of a minimum acceptable sound level.

The Commissioner concludes that it is not practical to quantitatively specify a minimum sound level which would be appropriate under all conditions, and for all products. The intent of the FDA is to assure that the emission indication is suitable to the particular product.

21. One comment on § 1040.10(g)(2), concerning labeling requirements, suggested that products subject to § 1040.10(g)(2)(i) be distinguished from products subject to § 1040.10(g)(2)(ii) by use of the designations "Class IIIa" and "Class IIIb" respectively, to indicate clearly that separate warnings apply. This comment further proposed that the content of the required warning labels be indicated by examples, rather than requiring specific language since this change would allow better use of the FDA labeling scheme by other regulatory agencies.

The Commissioner has concluded that there is a need for Class IIIa and IIIb designations to permit effective use of the FDA classification by other Federal agencies or state agencies. Accordingly, the label specification has been modified to include the separate designations. Reference to these designations for labeling purposes has been included in the definition of Class III laser products in § 1040.10(b)(7). With respect to the second suggestion, the Commissioner has concluded that permitting flexible wording on labels may lead to non-standard expressions that would inadequately express the appropriate warning.

22. Several comments concerning § 1040.10(g)(2)(ii) regarding Class III designation and warning suggested that the implied potential hazard from exposure to any part of the body is appropriate only above 5 milliwatts for visible emissions. A warning against eye exposure only, for exposures just below that level, was suggested by the comments.

The biological data upon which the accessible emission limits were based support the conclusion of the Commissioner that other body tissues, as well as the eye, may be at risk for visible emissions from Class III products at power levels less than 5 milliwatts. Limiting the warning to only eye exposure hazards, as suggested, would reduce user awareness of other possible dangers, and is therefore not acceptable.

23. Several comments concerning § 1040.10(g)(2)(ii) noted omission of the word "DIRECT" from the required wording for position 1 on the logotype.

The omission was inadvertent and the word has been included in the final rule.

24. One comment concerning § 1040.10(g)(4) indicated that the word "radiation" appearing on the required aperture label implies rays that are very hazardous, penetrating, and invisible, such as nuclear and x-radiation. Since apertures in most laser products do not emit this kind of radiation above the limits of Table III, the comment recommended that for such products the wording of the

label would be more appropriate if the word "laser" was inserted before the word "radiation."

The Commissioner agrees that the wording for the aperture label may be misleading, and, therefore, agrees to make the wording more appropriate to the laser product while still assuring radiation safety. Section 1040.10(g)(4) has been changed to require wording consistent with the specific type of radiation emitted.

25. One comment indicated that the basic concept of laser product classification is to identify the anticipated laser radiation hazard by a simple system, and therefore having the radiation output information as required by § 1040.10(g)(5) at position 2 on the required logotype is unnecessary because that information is inherently included in the classification information required for position 3. Another comment on § 1040.10(g)(5) stated that the maximum output appearing on the product could, by definition, have a magnitude greater than the accessible emissions used for classification, thus creating a confusing and unreasonable situation.

The Commissioner concludes that the laser product classification conveys information concerning the qualitative and semi-quantitative characteristics of the radiation hazard afforded by the laser product. The required radiation output information better quantifies the hazard, and thereby enables the user to develop an appropriate safety program. The Commissioner concludes that the maximum output could be clarified and therefore, to minimize the possible confusion resulting from its inclusion on the product, the definition of "maximum output" in § 1040.10(b)(21) has been revised by deleting the reference to "total" radiation emitted "in all directions." Also, § 1040.10(h)(1)(ii) concerning informational requirements has been amended to reflect more accurately the intent to provide the user with information on all emissions from a laser product.

26. One comment on § 1040.10(g)(7) concerning labels for defeatably interlocked protective housings stated that any interlock is defeatable, with the proper tools, so that the special case covered by this requirement needs clarification. Another comment suggested clarification of the applicability of this requirement to each "portion of the protective housing."

The Commissioner intended that § 1040.10(g)(7) apply only to "safety interlocks designed to allow safety interlock defeat," as described in § 1040.10(f)(2)(ii). Thus, labels must be provided for all safety interlocks for which the manufacturer gives directions in the user or service instructions for defeat in order to gain access to laser or collateral radiation, whether or not tools are required to defeat such interlocks. Warning labels would also be required for safety interlocks designed to be readily defeated without tools, whether or not directions are provided, such as an openly exposed interlock switch that merely has to be depressed or disconnected for defeat. The Commissioner agrees that clarification is needed and has revised paragraph (g)(6) and (7) in § 1040.10 to clarify the positioning of such labels and their applicability to removable portions of the protective housing, in addition to cross-referencing § 1040.10(f)(2)(ii).

27. Several comments indicated that in the proposal of December 10, 1973, § 1040.10(g)(10) permitted manufacturers to imprint the appropriate labels on the innermost container or packaging in which the laser product is supplied to the purchaser, if the largest surface area of the product is less than 25 square centimeters. The comments indicated that this concept was deleted in the proposal of September 4, 1974. It was requested that this provision be reinserted in the final rule.

The Commissioner concludes that it is not feasible to specify label proportions and minimum dimensions which would be appropriate for all of the great variety of laser products subject to the standard. Accordingly, the request is rejected. It should be noted that this section allows an alternate means of providing such labels if it can be demonstrated by the manufacturer that compliance is not technically feasible.

28. One comment on § 1040.10(h)(2)(ii) concerning servicing information stated that while manufacturers do not object to providing service instructions, they do object to having to provide such materials at cost to anyone who requests them. The comment also questioned the authority of FDA to regulate a manufacturer's pricing policy.

The Commissioner concludes that FDA has the authority to assure that radiation safety information is readily available. Since service instructions for radiation safety are required to be provided only upon request, any discouragement of subsequent purchase of this safety information by any person desiring to service a laser product should be minimized. By limiting the charge for such safety information to its actual cost, the availability is optimized without involving regulation of what is a fair pricing policy for manufacturers.

29. Two comments on § 1040.11(a)(3) concerning medical laser products stated that the requirement for an aperture label for such products was both unnecessary and misleading. It was argued that these devices are operated only by trained physicians who are thoroughly familiar with the product, thereby making the label unnecessary. Furthermore, the comments stated that the radiation aperture label would be confusing to hospital personnel and patients since the warning did not distinguish between laser and other types of radiation, such as x-rays. It was also pointed out that the label will be disturbing to the patient.

The Commissioner concludes that the the aperture label requirement for medical laser products is needed to minimize the possibility of accidental exposure to laser radiation through misuse of an unfamiliar product by either physicians or ancillary personnel. However, because of the possibility of confusing or disturbing patients or other nonmedical personnel, all reference to the emission of radiation has been deleted from the aperture label, and the requirement has been revised to apply only to apertures through which laser radiation is emitted.

30. One comment on § 1040.11(c) concerning demonstration laser products stated that the blink reflex and slight eye movements, which occur during maintained eye fixation, constitute a substantial degree of protection and that it has not been demonstrated that visible classroom lasers now in use represent a significant classroom hazard to justify the controls imposed.

The Commissioner concludes, on the basis of the available literature, that the blink reflex is not a reliable mechanism of protection. Published reports also indicate that under those circumstances where a blink can be elicited, an individual can override the reflex so that its potential utility would be negated. Thus, the possibility of human injury exists at these levels, particularly if some degree of fixation occurs.

Concerning the justification for the proposed special requirements for demonstration laser products, the Commissioner concludes that there are sufficient animal data to indicate a definite hazard at levels above the accessible emission limits in Table I–B. In addition, a field study conducted by FDA revealed that lasers are being used in demonstrations in ways which would cause unintended exposure to students. The Commissioner recognizes the educational value of demonstration laser products and does not intend to prohibit their continued use in a classroom environment. However, he concludes that a definite hazard to both students and instructors can exist in the classroom situation and appropriate safety features must be incorporated in those products intended by the manufacturer for demonstration purposes.

31. One comment stated that the product reporting provisions in 21 CFR 1002.61 should be revised to be compatible with new Part 1040.

The Commissioner agrees that revision of 21 CFR 1002.61 is necessary and concludes that appropriate revisions will be made prior to the effective date of Part 1040.

The Commissioner concludes that promulgation of this performance standard for laser products will not significantly affect the quality of the human environment and, therefore, that no environmental impact statement is necessary pursuant to 21 CFR Part 6 and 40 CFR Part 1500. The environmental impact analysis report and environmental assessment, along with other pertinent background data and information supporting the Commissioner's conclusions with respect to this standard are available for public review in the office of the Hearing Clerk, Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20852.

Therefore, pursuant to provisions of the Public Health Service Act, as amended by the Radiation Control for Health and

Safety Act of 1968 (sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f)) and under authority delegated to him (21 CFR 5.1), the Commissioner hereby amends Chapter I of Title 21 of the Code of Federal Regulations as follows:

1. In Part 1010:

a. By revising § 1010.1 to read as follows:

§ 1010.1 Scope.

The standards listed in this subchapter are prescribed pursuant to section 358 of the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f) and are applicable to electronic products as specified herein, to control electronic product radiation from such products. Standards so prescribed are subject to amendment or revocation and additional standards may be prescribed as are determined necessary for the protection of the public health and safety.

b. By revising paragraphs (a), (c), and (d) of § 1010.2 to read as follows:

§ 1010.2 Certification.

(a) Every manufacturer of an electronic product for which an applicable standard is in effect under this subchapter shall furnish to the dealer or distributor, at the time of delivery of such product, the certification that such product conforms to all applicable standards under this subchapter.

* * * * *

(c) Such certification shall be based upon a test, in accordance with the standard, of the individual article to which it is attached or upon a testing program which is in accordance with good manufacturing practices. The Director, Bureau of Radiological Health may disapprove such a testing program on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this subchapter.

(d) In the case of products for which it is not feasible to certify in accordance with paragraph (b) of this section, upon application by the manufacturer, the Director, Bureau of Radiological Health may approve an alternate means by which such certification may be provided.

c. By revising § 1010.3 to read as follows:

§ 1010.3 Identification.

(a) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall set forth the information specified in paragraph (a) (1) and (2) of this section. This information shall be provided in the form of a tag or label permanently affixed to or inscribed on such product so as to be legible and readily accessible to view when the product is fully assembled for use or in such other manner as may be prescribed in the applicable standard.

(1) The full name and address of the manufacturer of the product; abbreviations such as "Co.," "Inc.," or their foreign equivalents and the first and middle initials of individuals may be used. Where products are sold under a name other than that of the manufacturer of the product, the full name and address of the individual or company under whose name the product was sold may be set forth, provided such individual or company has previously supplied the Director, Bureau of Radiological Health with sufficient information to identify the manufacturer of the product.

(2) The place and month and year of manufacture: (i) The place of manufacture may be expressed in code provided the manufacturer has previously supplied the Director, Bureau of Radiological Health with the key to such code. (ii) The month and year of manufacture shall be provided clearly and legibly, without abbreviation, and with the year shown as a four-digit number as follows:

MANUFACTURED: (INSERT MONTH AND YEAR OF MANUFACTURE.)

(b) In the case of products for which it is not feasible to affix identification labeling in accordance with paragraph (a) of this section, upon application by the manufacturer, the Director, Bureau of Radiological Health may approve an alternate means by which such identification may be provided.

(c) Every manufacturer of an electronic product to which a standard under this subchapter is applicable shall provide to the Director, Bureau of Radiological Health, a list identifying each brand name which is applied to the product together with the full name and address of the individual or company for whom each product so branded is manufactured.

d. By revising § 1010.13 to read as follows:

§ 1010.13 Special test procedures.

The Director, Bureau of Radiological Health may, on the basis of a written application by a manufacturer, authorize test programs other than those set forth in the standards under this subchapter for an electronic product if he determines that such products are not susceptible to satisfactory testing by the procedures set forth in the standard and that the alternative test procedures assure compliance with the standard.

e. By revising § 1010.20 to read as follows:

§ 1010.20 Electronic products intended for export.

The performance standards prescribed in this subchapter shall not apply to any electronic product which is intended solely for export if:

(a) Such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and

(b) Such product meets all the applicable requirements of the country to which such product is intended for export.

2. By adding a new Part 1040 to read as follows:

Sec.
1040.10 Laser products.
1040.11 Specific purpose laser products.

AUTHORITY: Sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f).

§ 1040.10 Laser products.

(a) *Applicability.* The provisions of this section and § 1040.11 are applicable as specified herein to all laser products manufactured or assembled on or after August 2, 1976, except when such a laser product is:

(1) Sold to a manufacturer of an electronic product for use as a component (or replacement thereof) in such electronic product, or

(2) Sold by or for a manufacturer of an electronic product for use as a component (or replacement thereof) in such electronic product, provided that such laser product:

(i) Is accompanied by adequate instructions for installation in such electronic product,

(ii) Is labeled with a statement that it is designed for use solely as a component of such electronic product and therefore does not comply with the appropriate requirements of this section and § 1040.11 for complete laser products, and

(iii) Is not a removable laser system as described in paragraph (c) (2) of this section.

(b) *Definitions.* As used in this section and § 1040.11, the following definitions apply:

(1) "Accessible emission level" means the magnitude of emission from a laser product of laser or collateral radiation of a wavelength and emission duration to which human access is possible as measured pursuant to paragraph (e) of this section.

(2) "Accessible emission limit" means the maximum accessible emission level permitted within a particular class as set forth in paragraphs (c), (d), and (e) of this section.

(3) "Aperture" means any opening in the protective housing or other enclosure of a laser product through which laser or collateral radiation is emitted, thereby allowing human access to such radiation.

(4) "Aperture stop" means an opening serving to limit the size and to define the shape of the area over which radiation is measured.

(5) "Class I laser product" means any laser product which does not permit human access to laser radiation in excess of the accessible emission limits of Class I for any combination of emission duration and wavelength range.

(6) "Class II laser product" means any laser product which:

(i) Permits human access to laser radiation in excess of the accessible emission limits of Class I but not in excess of the accessible emission limits of Class II in the wavelength range of greater than 400 nanometers (nm) but less than or equal to 700 nm for emission durations greater than 0.25 second; and,

(ii) Does not permit human access to laser radiation in excess of the accessible

emission limits of Class I for any other combination of emission duration and wavelength range.

(7) "Class III laser product" means any laser product which permits human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class II, but which does not permit human access to laser radiation in excess of the accessible emission limits of Class III for any combination of emission duration and wavelength range. Class III laser products are separately designated as Class IIIa or Class IIIb laser products in labeling pursuant to paragraph (g)(2)(i) and (ii) of this section.

(8) "Class IV laser product" means any laser product which permits human access to laser radiation in excess of the accessible emission limits of Class III.

(9) "Collateral radiation" means any electronic product radiation, except laser radiation, emitted by a laser product as a result of or necessary for the operation of a laser incorporated into that product.

(10) "Demonstration laser product" means any laser product manufactured, designed, intended, or promoted for purposes of demonstration, entertainment, advertising display or artistic composition. The term "demonstration laser product" does not apply to laser products which are not manufactured, designed, intended, or promoted for such purposes, even though they may be used for those purposes or are intended to demonstrate other applications.

(11) "Emission duration" means the temporal duration of a pulse, a series of pulses, or continuous operation, expressed in seconds, during which human access to laser or collateral radiation could be permitted as a result of operation, maintenance or service of a laser product.

(12) "Human access" means access at a particular point to laser or collateral radiation by any part of the human body, by a straight line having an unobstructed length of 100 centimeters, or by any line having an unobstructed length of 10 centimeters, when laser or collateral radiation is incident at that point.

(13) "Integrated radiance" means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter per steradian ($Jcm^{-2}sr^{-1}$).

(14) "Irradiance" means the radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter (Wcm^{-2}).

(15) "Laser" means any device which can be made to produce or amplify electromagnetic radiation in the wavelength range of greater than 250 nm but less than or equal to 13,000 nm primarily by the process of controlled stimulated emission.

(16) "Laser energy source" means any device intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources such as electrical supply mains or batteries shall not be considered to constitute laser energy sources.

(17) "Laser product" means any manufactured product or assemblage of components which constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system which is intended for use as a component of an electronic product shall itself be considered a laser product.

(18) "Laser radiation" means all electromagnetic radiation emitted by a laser product within the spectral range specified in paragraph (b)(15) of this section which is produced as a result of controlled stimulated emission, or which is detectable with radiation so produced within the appropriate aperture stop specified in paragraph (e) of this section.

(19) "Laser system" means a laser in combination with an appropriate laser energy source with or without additional incorporated components.

(20) "Maintenance" means performance of those adjustments or procedures specified in user information provided by the manufacturer with the laser product which are to be performed by the user for the purpose of assuring the intended performance of the product. It does not include operation or service as defined in paragraph (b)(23) and (34) of this section.

(21) "Maximum output" means the maximum radiant power and, where applicable, the maximum radiant energy per pulse of accessible laser radiation emitted by a laser product during operation, as determined pursuant to paragraph (e) of this section.

(22) "Medical laser product" means any laser product manufactured, designed, intended or promoted for purposes of in vivo diagnostic, surgical, or therapeutic laser irradiation of any part of the human body.

(23) "Operation" means the performance of the laser product over the full range of its functions. It does not include maintenance or service as defined in paragraph (b)(20) and (34) of this section.

(24) "Protective housing" means those portions of a laser product which are designed to prevent human access to laser or collateral radiation in excess of the prescribed accessible emission limits under conditions specified in this section and in § 1040.11.

(25) "Pulse duration" means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.

(26) "Radiance" means radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian ($Wcm^{-2}sr^{-1}$).

(27) "Radiant energy" means energy emitted, transferred or received in the form of radiation, expressed in joules (J).

(28) "Radiant exposure" means the radiant energy incident on an element of a surface divided by the area of that element, expressed in joules per square centimeter (Jcm^{-2}).

(29) "Radiant power" means power emitted, transferred or received in the form of radiation, expressed in watts (W).

(30) "Remote control connector" means an electrical connector which permits the connection of external controls placed apart from other components of the laser product to prevent human access to all laser and collateral radiation in excess of the limits specified in this section and in § 1040.11.

(31) "Safety interlock" means a device associated with the protective housing of a laser product to prevent human access to excessive radiation in accordance with paragraph (f)(2) of this section.

(32) "Sampling interval" means the time interval during which the level of accessible laser or collateral radiation is sampled by a measurement process. The magnitude of the sampling interval in units of seconds is represented by the symbol (t).

(33) "Scanned laser radiation" means laser radiation having a time-varying direction, origin or pattern of propagation with respect to a stationary frame of reference.

(34) "Service" means the performance of those procedures or adjustments described in the manufacturer's service instructions which may affect any aspect of the product's performance for which this section and § 1040.11 have applicable requirements. It does not include maintenance or operation as defined in paragraph (b)(20) and (23) of this section.

(35) "Surveying, leveling, or alignment laser product" means a laser product manufactured, designed, intended or promoted for one or more of the following uses:

(i) Determining and delineating the form, extent, or position of a point, body, or area by taking angular measurement.

(ii) Positioning or adjusting parts in proper relation to one another.

(iii) Defining a plane, level, elevation, or straight line.

(36) "Warning logotype" means a logotype as illustrated in either Figure 1 or Figure 2 of paragraph (g) of this section.

(37) "Wavelength" means the propagation wavelength in air of electromagnetic radiation.

(c) *Classification of laser products*—(1) *All laser products.* Each laser product shall be classified in accordance with definitions set forth in paragraph (b)(5) through (8) of this section on the basis of that combination of emission level(s), emission duration(s), and wavelength(s) of accessible laser radiation emitted during operation which results, at any time after manufacture, in the highest class specified in Tables I–A, I–B, and I–C of paragraph (d) of this section pursuant to paragraphs (d) and (e) of this section. For purposes of classification, Class II is higher than Class I, Class III is higher than Class II, and Class IV is higher than Class III.

(2) *Removable laser systems.* Any laser system which is incorporated into

a laser product subject to the requirements of this section and which is capable, without modification, of producing laser radiation when removed from such laser product, shall itself be considered a laser product and shall be separately subject to the applicable requirements in this subchapter for laser products of its class. It shall be classified on the basis of accessible emission of laser radiation when so removed.

(d) *Accessible emission limits.* Accessible emission limits for laser radiation in each class are specified in Tables I–A, I–B, and I–C of this paragraph in terms of the factors, k_1 and k_2, for different ranges of wavelength and emission duration. These factors are given in Table II–A of this paragraph, with selected numerical values in Table II–B of this paragraph, for various subranges of wavelength and sampling interval. The accessible emission limits in Tables I–A, I–B, and I–C of this paragraph are also expressed in terms of the sampling interval (t) for some ranges of emission duration; and the correction factors in Table II–A of this paragraph are expressed in terms of the specific wavelength (λ) and sampling interval (t) for some subranges of wavelength and sampling interval. Accessible emission limits for collateral radiation are specified in Table III of this paragraph.

TABLE I–A

CLASS I ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration (seconds)	Class I – Accessible emission limits
>250 but ≤400	$\leq 3.0 \times 10^{4}$	$2.4 \times 10^{-5} k_1 k_2$ J*
	$> 3.0 \times 10^{4}$	$8.0 \times 10^{-10} k_1 k_2 t$ J
>400 but ≤1400	$> 1.0 \times 10^{-9}$ to 2.0×10^{-5}	$2.0 \times 10^{-7} k_1 k_2$ J
	$> 2.0 \times 10^{-5}$ to 1.0×10^{1}	$7.0 \times 10^{-4} k_1 k_2 t^{3/4}$ J
	$> 1.0 \times 10^{1}$ to 1.0×10^{4}	$3.9 \times 10^{-3} k_1 k_2$ J
	$> 1.0 \times 10^{4}$	$3.9 \times 10^{-7} k_1 k_2 t$ J
	OR**	
	$> 1.0 \times 10^{-9}$ to 1.0×10^{1}	$10 k_1 k_2 t^{1/3}$ J cm^{-2} sr^{-1}
	$> 1.0 \times 10^{1}$ to 1.0×10^{4}	$20 k_1 k_2$ J cm^{-2} sr^{-1}
	$> 1.0 \times 10^{4}$	$2.0 \times 10^{-3} k_1 k_2 t$ J cm^{-2} sr^{-1}
>1400 but ≤13000	$> 1.0 \times 10^{-9}$ to 1.0×10^{-7}	$7.9 \times 10^{-5} k_1 k_2$ J
	$> 1.0 \times 10^{-7}$ to 1.0×10^{1}	$4.4 \times 10^{-3} k_1 k_2 t^{1/4}$ J
	$> 1.0 \times 10^{1}$	$7.9 \times 10^{-4} k_1 k_2 t$ J

* Class I accessible emission limits for the wavelength range of greater than 250 nm but less than or equal to 400 nm shall not exceed the Class I accessible emission limits for the wavelength range of greater than 1400 nm but less than or equal to 13000 nm with a k_1 and k_2 of 1.0 for comparable sampling intervals.

**Instructions for the Class I dual limits are set forth in paragraph (d)(4) of this section.

TABLE I–B

CLASS II ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration (seconds)	Class II – Accessible emission limits
>400 but ≤700	$> 2.5 \times 10^{-1}$	$1.0 \times 10^{-3} k_1 k_2 t$ J

TABLE I–C

CLASS III ACCESSIBLE EMISSION LIMITS FOR LASER RADIATION

Wavelength (nanometers)	Emission duration (seconds)	Class III – Accessible emission limits
>250 but ≤400	$\leq 2.5 \times 10^{-1}$	$3.8 \times 10^{-4} k_1 k_2$ J
	$> 2.5 \times 10^{-1}$	$1.5 \times 10^{-3} k_1 k_2 t$ J
>400 but ≤1400	$> 1.0 \times 10^{-9}$ to 2.5×10^{-1}	$10 k_1 k_2 t^{1/3}$ J cm^{-2} to a maximum value of 10 J cm^{-2}
	$> 2.5 \times 10^{-1}$	$5.0 \times 10^{-1} t$ J
>1400 but ≤13000	$> 1.0 \times 10^{-9}$ to 1.0×10^{1}	10 J cm^{-2}
	$> 1.0 \times 10^{1}$	$5.0 \times 10^{-1} t$ J

TABLE II–A

VALUES OF WAVELENGTH DEPENDENT CORRECTION FACTORS k_1 AND k_2

Wavelength (nanometers)	k_1	k_2		
250 to 302.4	1.0	1.0		
>302.4 to 315	$10^{\left[\frac{\lambda - 302.4}{5}\right]}$	1.0		
>315 to 400	330.0	1.0		
>400 to 700	1.0	1.0		
>700 to 800	$10^{\left[\frac{\lambda - 700}{515}\right]}$	If: $t \leq \frac{10100}{\lambda - 699}$ then: $k_2 = 1.0$	If: $\frac{10100}{\lambda - 699} < t \leq 10^4$ then: $k_2 = \frac{t(\lambda - 699)}{10100}$	If: $t > 10^4$ then: $k_2 = \frac{\lambda - 699}{1.01}$
>800 to 1060	$10^{\left[\frac{\lambda - 700}{515}\right]}$	If: $t \leq 100$ then: $k_2 = 1.0$	If: $100 < t \leq 10^4$ then: $k_2 = \frac{t}{100}$	If: $t > 10^4$ then: $k_2 = 100$
>1060 to 1400	5.0			
>1400 to 1535	1.0	1.0		
>1535 to 1545	$t \leq 10^{-7}$ $k_1 = 100.0$	1.0		
	$t > 10^{-7}$ $k_1 = 1.0$			
>1545 to 13000	1.0	1.0		

Note: The variables in the expressions are the magnitudes of the sampling interval (t), in units of seconds, and the wavelength (λ), in units of nanometers.

TABLE II–B

SELECTED NUMERICAL SOLUTIONS FOR k_1 AND k_2

Wavelength (nanometers)	k_1	k_2				
		$t \leq 100$	$t = 300$	$t = 1000$	$t = 3000$	$t \geq 10{,}000$
250	1.0	1.0				
300	1.0					
302	1.0					
303	1.32					
304	2.09					
305	3.31					
306	5.25					
307	8.32					
308	13.2					
309	20.9					
310	33.1					
311	52.5					
312	83.2					
313	132.0					
314	209.0					
315	330.0					
400	330.0					
401	1.0					
600	1.0					
600	1.0					
700	1.0					
710	1.05	1	1	1.1	3.3	11.0
720	1.09	1	1	2.1	6.3	21.0
730	1.14	1	1	3.1	9.3	31.0
740	1.20	1	1.2	4.1	12.0	41.0
750	1.25	1	1.5	5.0	15.0	50.0
760	1.31	1	1.8	6.0	18.0	60.0
770	1.37	1	2.1	7.0	21.0	70.0
780	1.43	1	2.4	8.0	24.0	80.0
790	1.50	1	2.7	9.0	27.0	90.0
800	1.56	1	3.0	10.0	30.0	100.0
850	1.96	1	3.0	10.0	30.0	100.0
900	2.44	1	3.0	10.0	30.0	100.0
950	3.05	1	3.0	10.0	30.0	100.0
1000	3.82	1	3.0	10.0	30.0	100.0
1050	4.78	1	3.0	10.0	30.0	100.0
1000	5.00	1	3.0	10.0	30.0	100.0
1100	5.00	1	3.0	10.0	30.0	100.0
1400	5.00	1	3.0	10.0	30.0	100.0
1500	1.0	1.0				
1540	100.0*					
1600	1.0					
13000	1.0					

*The factor $k_1 = 100.0$ when $t \leq 10^{-7}$, and $k_1 = 1.0$ when $t > 10^{-7}$

Note: The variable (t) is the magnitude of the sampling interval in units of seconds.

Notes applicable to Tables I–A, I–B, and I–C:

(1) The quantities presented in the tables are radiant energy expressed in joules (J); radiant exposure expressed in joules per square centimeter (Jcm^{-2}); and integrated radiance expressed in joules per square centimeter per steradian ($Jcm^{-2}\,sr^{-1}$).

(2) The factors k_1 and k_2 are wavelength dependent correction factors determined from Table II–A.

(3) The variable t in the expressions of emission limits is the magnitude of the sampling interval in units of seconds.

(4) An accessible emission limit containing the units of joules, when divided by the sampling interval (t), is equivalent to an accessible emission limit containing the units of watts.

TABLE III

ACCESSIBLE EMISSION LIMITS FOR COLLATERAL RADIATION FROM LASER PRODUCTS

1. *Accessible emission limits* for collateral radiation having wavelengths greater than 250 nm but less than or equal to 13,000 nm are identical to the accessible emission limits of Class I laser radiation, as determined from Tables I–A and II–A in this paragraph, for the appropriate ranges of wavelength and emission duration.

2. *Accessible emission limit* for collateral radiation within the x-ray range of wavelengths is 0.5 milliroentgen in an hour, averaged over a cross-section parallel to the external surface of the product, having an area of 10 square centimeters with no dimension greater than 5 centimeters.

(1) *Beam of a single wavelength.* Laser or collateral radiation of a single wavelength exceeds the accessible emission limits of a class if its accessible emission level is greater than the accessible emission limit of that class within any of the ranges of emission duration specified in Tables I–A, I–B, and I–C of this paragraph.

(2) *Beam of multiple wavelengths in same range.* Laser or collateral radiation, having two or more wavelengths within any one of the wavelength ranges specified in Tables I–A, I–B, and I–C of this paragraph, exceeds the accessible emission limits of a class if the sum of the ratios of the accessible emission level to the corresponding accessible emission limit at each such wavelength is greater than unity for that combination of emission duration and wavelength distribution which results in the maximum sum.

(3) *Beam with multiple wavelengths in different ranges.* Laser or collateral radiation having wavelengths within two or more of the wavelength ranges specified in Tables I–A, I–B, and I–C of this paragraph exceeds the accessible emission limits of a class if it exceeds the applicable limits within any one of those wavelength ranges. This determination is made for each wavelength range in accordance with paragraph (d) (1) or (2) of this section.

(4) *Class I dual limits.* Laser or collateral radiation in the wavelength range of greater than 400 nm but less than or equal to 1,400 nm exceeds the accessible emission limits of Class I if it exceeds both:

(i) The Class I accessible emission limits for radiant energy within any range of emission duration specified in Table I–A of this paragraph and,

(ii) The Class I accessible emission limits for integrated radiance within any range of emission duration specified in Table I–A of this paragraph.

(e) *Tests for determination of compliance.*—(1) *Tests for certification.* Tests on which certification pursuant to § 1010.2 of this chapter is based shall account for all errors and statistical uncertainties in the measurement process. Because compliance with the standard is required for the useful life of a product, such tests shall also account for increases in emission and degradation in radiation safety with age.

(2) *Test conditions.* Except as provided in § 1010.13 of this chapter, tests for compliance with each of the applicable requirements of this section and § 1040.11 shall be made during operation, maintenance or service as appropriate:

(i) Under those conditions and procedures which maximize the accessible emission levels, including start-up, stabilized emission, and shut-down of the laser product; and,

(ii) With all controls and adjustments listed in the operation, maintenance, and service instructions adjusted in combination to result in the maximum accessible emission level of radiation; and,

(iii) At points in space to which human access is possible in the product configuration which is necessary to determine compliance with each requirement, e.g., if operation may require removal of portions of the protective housing and defeat of safety interlocks, measurements shall be made at points accessible in that product configuration; and,

(iv) With the measuring instrument detector so positioned and so oriented with respect to the laser product as to result in the maximum detection of radiation by the instrument; and,

(v) For a laser product other than a laser system, with the laser coupled to that type of laser energy source which is specified as compatible by the laser product manufacturer and which produces the maximum emission level of accessible radiation from that product.

(3) *Measurement parameters.* Accessible emission levels of laser and collateral radiation shall be based upon the following measurements as appropriate, or their equivalent:

(i) The radiant power (W) or radiant energy (J) detectable within a circular aperture stop having a diameter of 80 millimeters (except for scanned laser radiation).

(ii) The irradiance (Wcm^{-2}) or radiant exposure (Jcm^{-2}) averaged over a circular aperture stop having a diameter of 7 millimeters.

(iii) The radiance ($Wcm^{-2}sr^{-1}$) or integrated radiance ($Jcm^{-2}sr^{-1}$) which is equivalent to the radiant power (W) or radiant energy (J) detectable through a circular aperture stop having a diameter of 7 millimeters and within an effective solid angle of acceptance of 10^{-4}sr, divided by that solid angle (sr) and by the area of the aperture stop (cm^2).

(4) *Measurement parameters for scanned laser radiation.* Accessible emission levels of scanned laser radiation shall be based upon the measurement of radiation detectable within a stationary circular aperture stop having a 7-millimeter diameter. The resulting temporal variation of detected radiation shall be considered as a pulse or series of pulses.

(f) *Performance requirements*—(1) *Protective housing.* Each laser product, regardless of its class, shall have a protective housing which, when in place, prevents human access during operation to:

(i) Laser radiation in excess of the accessible emission limits of Class I wherever and whenever human access to laser radiation exceeding the limits of Class I is not necessary for the performance of the function(s) of the product; and,

(ii) Laser radiation in excess of the accessible emission limits of Class II wherever and whenever human access to laser radiation exceeding the limits of Class II is not necessary for the performance of the function(s) of the product; and,

(iii) Laser radiation in excess of the accessible emission limits of Class III wherever and whenever human access to laser radiation exceeding the limits of Class III is not necessary for the performance of the function(s) of the product; and,

(iv) Collateral radiation in excess of the accessible emission limits specified in Table III in paragraph(d) of this section wherever and whenever human access to collateral radiation in excess of those limits is not necessary for the performance of the function(s) of the product.

(2) *Safety interlocks.* (i) Each laser product, regardless of its class, shall be provided with a safety interlock for each portion of the protective housing which is designed to be removed or displaced during operation or maintenance, if removal or displacement of such portion of the protective housing could permit human access to laser or collateral radiation in excess of the accessible emission limits applicable under paragraph (f)(1) of this section. Each required safety interlock, unless defeated, shall:

(*a*) Prevent such human access to laser and collateral radiation upon removal or displacement of such portion of the protective housing; and,

(*b*) Preclude removal or displacement of such portion of the protective housing upon failure to prevent human access to laser and collateral radiation as required in paragraph(f)(2)(i)(*a*) of this section.

(ii) Laser products which incorporate safety interlocks designed to allow safety interlock defeat shall incorporate a means of visual or aural indication of interlock defeat. During interlock defeat, such indication shall be visible or audible whenever the laser product is energized, with and without the associated portion of the protective housing removed or displaced.

(iii) Replacement of a removed or displaced portion of the protective housing shall not be possible while required safety interlocks are defeated.

(3) *Remote control connector.* Each laser system classified as a Class III or IV laser product shall incorporate a readily accessible remote control connector having an electrical potential difference on the remote control connector no greater than 130 root-mean-square volts. When the terminals of the connector are not electrically joined, human access to all laser and collateral radiation from the laser product in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section shall be prevented.

(4) *Key control.* Each laser system classified as a Class III or IV laser product shall incorporate a key-actuated master control. The key shall be removable and the laser shall not be operable when the key is removed.

(5) *Laser radiation emission indicator.* (i) Each laser system classified as a Class II laser product shall incorporate an emission indicator which provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I.

(ii) Each laser system classified as a Class III or IV laser product shall incorporate an emission indicator which provides a visible or audible signal during emission of accessible laser radiation in excess of the accessible emission limits of Class I, and sufficiently prior to emission of such radiation to allow appropriate action to avoid exposure to the laser radiation.

(iii) If the laser and laser energy source are housed separately and can be operated at a separation distance of greater than 2 meters, both laser and laser energy source shall incorporate an emission indicator as required in accordance with paragraphs (f)(5)(i) or (ii) of this section.

(iv) Any visible signal required by paragraphs (f)(5)(i) or (ii) of this section shall be clearly visible through protective eyewear designed specifically for the wavelength(s) of the emitted laser radiation.

(v) Emission indicators required by paragraph (f)(5)(i) or (ii) of this section shall be located so that viewing does not require human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and Table III.

(6) *Beam attenuator.* Each laser system classified as a Class II, III, or IV laser product shall be provided with one or more permanently attached means, other than laser energy source switch (es), electrical supply main connectors or the key-actuated master control, capable of preventing human access to all laser and collateral radiation in excess of the accessible emission limits of Class I and Table III.

(7) *Location of controls.* Each Class II, III, or IV laser product shall have operational and adjustment controls located so that human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section is unnecessary for operation or adjustment of such controls.

(8) *Viewing optics.* All viewing optics, viewports, and display screens incorporated into a laser product, regardless of its class, shall attenuate at all times the accessible levels of transmitted laser and collateral radiation to less than the accessible emission limits of Class I and Table III of paragraph (d) of this section. For any shutter or variable attenuator incorporated into such viewing optics, viewports, or display screens, a means shall be provided:

(i) To prevent human access to laser and collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section whenever the shutter is opened or the attenuator varied; and,

(ii) To preclude, upon failure of such means as required in paragraph (f)(8)(i) of this section, opening the shutter or varying the attenuator when human access is possible to transmitted laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section.

(9) *Scanning safeguard.* Laser products which emit accessible scanned laser radiation shall not, as a result of scan failure or other failure causing a change in either scan velocity or amplitude, permit human access to laser radiation in excess of the accessible emission limit(s) which are applicable to the scanned laser radiation.

(g) *Labeling requirements.* In addition to the requirements of §§ 1010.2 and 1010.3 of this chapter, each laser product

shall be subject to the applicable labeling requirements of this paragraph.

(1) *Class II designation and warning.* Each Class II laser product shall have affixed a label bearing the warning logotype A (Figure 1 in this paragraph) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—DO NOT STARE INTO BEAM";

and

[Position 3 on the logotype]

"CLASS II LASER PRODUCT".

WARNING LOGOTYPE A

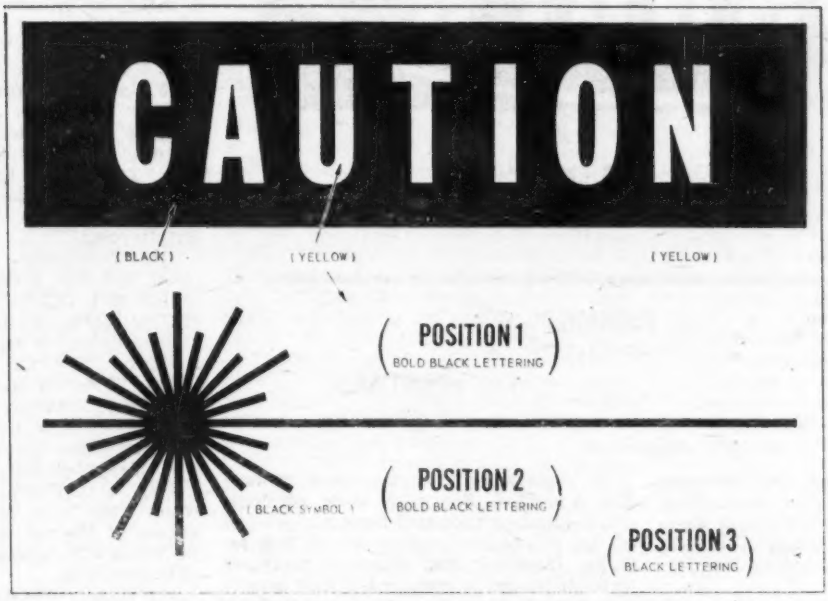

Figure 1

(2) *Class III designation and warning.* (i) Each laser product classified in Class III solely because of the emission of accessible laser radiation for emission durations greater than 3.8×10^{-4} second and in the wavelength range of greater than 400 nm but less than or equal to 700 nm, with an irradiance of less than or equal to 2.5×10^{-3} W/cm^{-2} and with a radiant power of less than or equal to 5.0×10^{-3} W shall have affixed a label bearing the warning logotype A (Figure 1 of paragraph (g)(1) of this section) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS"; and,

[Position 3 on the logotype]

"CLASS IIIa LASER PRODUCT".

(ii) Each Class III laser product other than those described in paragraph (g)(2)(i) of this section shall have affixed a label bearing the warning logotype B (Figure 2 in this paragraph) and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—AVOID DIRECT EXPOSURE TO BEAM"; and,

[Position 3 on the logotype]

"CLASS IIIb LASER PRODUCT".

WARNING LOGOTYPE B

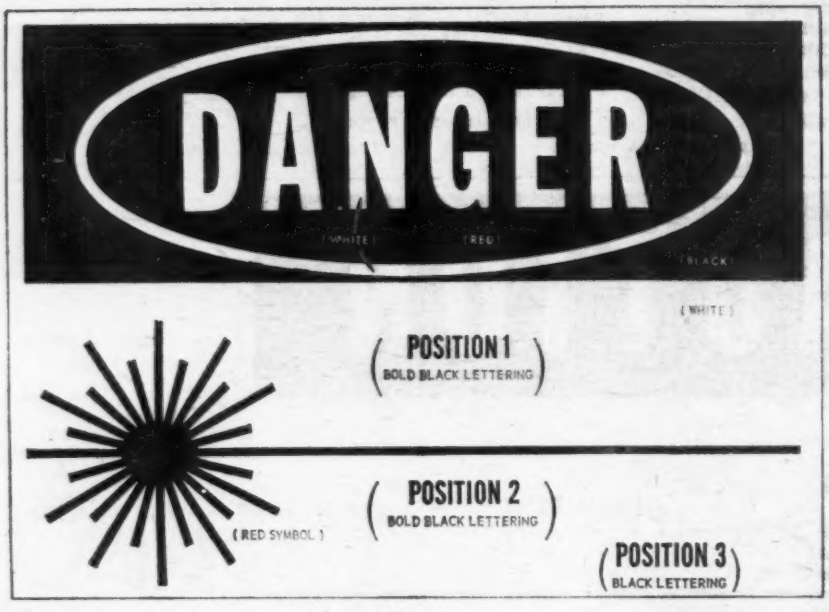

Figure 2

(3) *Class IV designation and warning.* Each Class IV laser product shall have affixed a label bearing the warning logotype B (Figure 2 of paragraph (g) (2) (ii) of this section), and including the following wording:

[Position 1 on the logotype]

"LASER RADIATION—AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION"; and,

[Position 3 on the logotype]

"CLASS IV LASER PRODUCT".

(4) *Aperture label.* Each laser product, except medical laser products, shall have affixed, in close proximity to each aperture through which is emitted accessible laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section, a label(s) bearing the following wording as applicable:

(i) "AVOID EXPOSURE—Laser radiation is emitted from this aperture," if the radiation emitted through such aperture is laser radiation.

(ii) "AVOID EXPOSURE—Hazardous electromagnetic radiation is emitted from this aperture," if the radiation emitted through such aperture is collateral radiation described in Table III, item 1.

(iii) "AVOID EXPOSURE—Hazardous x-rays are emitted from this aperture," if the radiation emitted through such aperture is collateral radiation described in Table III, item 2.

(5) *Radiation output information.* Each Class II, III, and IV laser product shall state in appropriate units, at position 2 on the required warning logotype, the maximum output of laser radiation, the pulse duration when appropriate, and the laser medium or emitted wavelength(s).

(6) *Labels for noninterlocked protective housings.* For each laser product, labels shall be provided for each portion of the protective housing which has no safety interlock and which is designed to be displaced or removed during operation, maintenance or service, and thereby could permit human access to laser or collateral radiation in excess of the limits of Class I and Table III in paragraph (d) of this section. Such labels shall be visible on the protective housing prior to displacement or removal of such portion of the protective housing and visible on the product in close proximity to the opening created by removal or displacement of such portion of the protective housing, and shall include the wording:

(i) "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM." for accessible laser radiation:

(*a*) In excess of the accessible emission limits of Class I for emission durations greater than 0.25 second and in the wavelength range greater than 400 nm but less than or equal to 700 nm; and,

(*b*) Not in excess of the accessible emission limits of Class II; and,

(*c*) Not in excess of the accessible emission limits of Class I for any other combination of emission duration and wavelength range.

(ii) "CAUTION—Laser radiation when open. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for accessible laser radiation:

(*a*) In excess of the accessible emission limits of Class II; and,

(*b*) In excess of neither an irradiance of 2.5×10^{-3} Wcm^{-2} nor a radiant power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nm but less than or equal to 700 nm; and,

(*c*) Not in excess of the accessible emission limits of Class I for any other combination of emission duration and wavelength range.

(ii) "DANGER—Laser radiation when open. AVOID DIRECT EXPOSURE TO BEAM." for accessible laser radiation:

(*a*) Not in excess of the accessible emission limits of Class III for any combination of emission duration and wavelength range; and either,

(*b*) In excess of either an irradiance of 2.5×10^{-3} Wcm^{-2} or a radiant power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nm but less than or equal to 700 nm; or,

(*c*) In excess of the accessible emission limits of Class I for any other combination of emission duration and wavelength range.

(iv) "DANGER—Laser radiation when open. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for accessible laser radiation in excess of the accessible emission limits of Class III.

(v) "CAUTION—Hazardous electromagnetic radiation when open." for collateral radiation in excess of the accessible emission limits in Table III, item 1 of paragraph (d) of this section.

(vi) "CAUTION—Hazardous x-rays when open." for collateral radiation in excess of the accessible emission limits in Table III, item 2 of paragraph (d) of this section.

(7) *Labels for defeatably interlocked protective housings.* For each laser product, labels shall be provided for each defeatably interlocked (as described in paragraph (f) (2) (ii) of this section) portion of the protective housing which is designed to be displaced or removed during operation, maintenance or service, and which upon interlock defeat could permit human access to laser or collateral radiation in excess of the limits of Class I or Table III in paragraph (d) of this section. Such labels shall be visible on the product prior to and during interlock defeat and in close proximity to the opening created by the removal or displacement of such portion of the protective housing, and shall include the wording:

(i) "CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM." for accessible laser radiation:

(*a*) In excess of the accessible emission limits of Class I for emission durations greater than 0.25 second and in the wavelength range greater than 400 nm but less than or equal to 700 nm; and,

(*b*) Not in excess of the accessible emission limits of Class II; and,

(*c*) Not in excess of the accessible emission limits of Class I for any other combination of emission duration and wavelength range.

(ii) "CAUTION—Laser radiation when open and interlock defeated. DO NOT STARE INTO BEAM OR VIEW DIRECTLY WITH OPTICAL INSTRUMENTS." for accessible laser radiation:

(*a*) In excess of the accessible emission limits of Class II; and,

(b) In excess of neither an irradiance of 2.5×10^{-3} Wcm^{-2} nor a radiant power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nm but less than or equal to 700 nm; and,

(c) Not in excess of the accessible emission limits of Class I for any other combination of emission duration and wavelength range.

(iii) "DANGER—Laser radiation when open and interlock defeated. AVOID DIRECT EXPOSURE TO BEAM." for accessible laser radiation:

(a) Not in excess of the accessible emission limits of Class III for any combination of emission duration and wavelength range; and either,

(b) In excess of either an irradiance of 2.5×10^{-3} Wcm^{-2} or a radiant power of 5.0×10^{-3} W for emission durations greater than 3.8×10^{-4} second for wavelengths greater than 400 nm but less than or equal to 700 nm; or,

(c) In excess of the accessible emission limits of Class I for any other combination of emission duration and wavelength range.

(iv) "DANGER—Laser radiation when open and interlock defeated. AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION." for accessible laser radiation in excess of the accessible emission limits of Class III.

(v) "CAUTION—Hazardous electromagnetic radiation when open and interlock defeated." for collateral radiation in excess of the accessible emission limits in Table III, item 1 of paragraph (d) of this section.

(vi) "CAUTION—Hazardous x-rays when open and interlock defeated." for collateral radiation in excess of the accessible emission limits in Table III, item 2 of paragraph (d) of this section.

(8) *Warning for invisible radiation.* On the labels specified in this paragraph, if the wavelength(s) of the laser or collateral radiation referred to is:

(i) Less than or equal to 400 nm or greater than 700 nm, the word "invisible" shall appropriately precede the word "radiation"; or,

(ii) In a range specified in paragraph (g) (8) (i) of this section and also within the range of greater than 400 nm but less than or equal to 700 nm, the words "visible and invisible" shall appropriately precede the word "radiation."

(9) *Positioning of labels.* All labels affixed to a laser product shall be positioned so as to make unnecessary, during reading, human exposure to laser or collateral radiation in excess of the accessible emission limits of Class I and Table III of paragraph (d) of this section.

(10) *Label specifications.* Labels required by this section and § 1040.11 shall be permanently affixed to the laser product, legible, and clearly visible during operation, maintenance or service as appropriate. If the size, configuration, or design of the laser product would preclude compliance with the requirements for any required label, the Director, Bureau of Radiological Health, upon written application by the manufacturer, may approve alternate means of providing such label(s).

(h) *Informational requirements*—(1) *User information.* Manufacturers of laser products shall provide as an integral part of any user instruction or operation manual which is regularly supplied with the product, or, if not so supplied, shall cause to be provided with each laser product:

(i) Adequate instructions for assembly, operation and maintenance, including clear warnings concerning precautions to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables I–A, I–B, I–C and III of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11.

(ii) A statement of the magnitude, in appropriate units, of the pulse duration(s), maximum radiant power and, where applicable, the maximum radiant energy per pulse of the accessible laser radiation detectable in each direction in excess of the accessible emission limits in Table I–A of paragraph (d) of this section determined pursuant to paragraph (e) of this section.

(iii) Legible reproductions (color optional) of all labels and hazard warnings required by paragraph (g) of this section and § 1040.11 to be affixed to the laser product or provided with the laser product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 or 2 of paragraph (g) (1) and (2) (ii) of this section). The corresponding position of each label affixed to the product shall be indicated or, if provided with the product, a statement that such labels could not be affixed to the product but were supplied with the product and a statement of the form and manner in which they were supplied shall be provided.

(iv) A listing of all controls, adjustments and procedures for operation and maintenance, including the warning "Caution—use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure."

(v) In the case of laser products other than laser systems, a statement of the compatibility requirements for a laser energy source that will assure compliance of the laser product with this section and § 1040.11.

(2) *Purchasing and servicing information.* Manufacturers of laser products shall provide or cause to be provided:

(i) In all catalogs, specification sheets, and descriptive brochures pertaining to each laser product, a legible reproduction (color optional) of the warning logotype required to be affixed to that product, including the information required for positions 1, 2, and 3 of the applicable logotype (Figure 1 or 2 of paragraph (g) (1) and (2) (ii) of this section).

(ii) To servicing dealers and distributors and to others upon request at a cost not to exceed the cost of preparation and distribution, adequate instructions for service adjustments and service procedures for each laser product model, including clear warnings and precautions to be taken to avoid possible exposure to laser and collateral radiation in excess of the accessible emission limits in Tables I–A, I–B, I–C and III of paragraph (d) of this section, and a schedule of maintenance necessary to keep the product in compliance with this section and § 1040.11; and, in all such service instructions a listing of those controls and procedures which could be utilized by persons other than the manufacturer or his agents to increase accessible emission levels of radiation, and a clear description of the location of displaceable portions of the protective housing which could allow access to laser or collateral radiation in excess of the accessible emission limits in Tables I–A, I–B, I–C and III of paragraph (d) of this section. The instructions shall include protective procedures for service personnel, and legible reproductions (color optional) of required labels and hazard warnings.

(i) *Modification of a certified product.* The modification of a laser product, previously certified pursuant to § 1010.2 of this chapter, by any person engaged in the business of manufacturing, assembling or modifying laser products shall be construed as manufacturing under the act if the modification affects any aspect of the product's performance or intended function(s) for which this section and § 1040.11 have an applicable requirement. The manufacturer who performs such modification shall recertify and reidentify the product in accordance with the provisions of §§ 1010.2 and 1010.3 of this chapter.

§ 1040.11 Specific purpose laser products.

(a) *Medical laser products.* Each medical laser product shall comply with all of the applicable requirements of § 1040.10 for laser products of its class. In addition, the manufacturer shall:

(1) Incorporate in each Class III or IV medical laser product a means for the measurement of the level of that laser radiation intended for irradiation of the human body with an error in measurement of no more than ±20 percent when calibrated in accordance with paragraph (a) (2) of this section. Indication of the measurement shall be in International System Units.

(2) Supply with each Class III or IV medical laser product instructions specifying a procedure and schedule for calibration of the measurement system required by paragraph (a) (1) of this section.

(3) Affix to each medical laser product, in close proximity to each aperture through which is emitted accessible laser radiation in excess of the accessible emission limits of Class I, a label bearing the wording: "Laser aperture."

(b) *Surveying, leveling, and alignment laser products.* Each surveying, leveling, or alignment laser product shall comply with all of the applicable requirements of § 1040.10 for a Class I, Class II, or Class III laser product and, in addition:

(1) Shall not permit human access to laser radiation in the wavelength range of greater than 400 nm but less than or equal to 700 nm with a radiant power that exceeds 5.0×10^{-3} W for any emission duration greater than 3.8×10^{-4} second; and,

(2) Shall not permit human access to laser radiation in excess of the accessible emission limits of Class I for any other combination of emission duration and wavelength range.

(c) *Demonstration laser products.* Each demonstration laser product shall comply with all of the applicable requirements of § 1040.10 for a Class I or Class II laser product and shall not permit human access to laser radiation in excess of the accessible emission limits of Class I and, if applicable, Class II.

Effective date. This order shall become effective on August 2, 1976.

(Sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f).)

Dated: July 1, 1975.

SAM D. FINE,
Associate Commissioner for Compliance.

[FR Doc.75–17892 Filed 7–30–75;8:45 am]